April 23, 2015

Alexion Reports First Quarter 2015 Results

- Soliris Net Product Sales Increased to $600.3 Million; 25 Percent Growth Compared to Year-ago In-quarter Sales, Despite Increased Currency Headwinds -

- Steady Soliris Growth in PNH and aHUS Worldwide -

- Regulatory Processes for Strensiq™ (asfotase alfa) Ongoing in the U.S., Europe and Japan -

- Three Eculizumab Registration Programs Enrolling in MG, NMO and DGF; Four Additional Highly Innovative Molecules in Clinical Development -

- Complement Inhibitor Portfolio Strengthened and Now Includes 7 Molecules Across Diverse Platforms -

- 17 Preclinical Development Programs Underway Spanning Multiple Modalities and Therapeutic Areas Targeting Devastating and Rare Disorders -

First Quarter 2015 Financial Highlights:

- Q1 2015 net product sales increased to $600.3 million, compared to $566.6 million in Q1 2014. Excluding $87.8 million recognized in Q1 2014 for reimbursement of shipments in prior years, net product sales increased 25 percent year-on-year.
- Q1 2015 GAAP EPS was $0.45 per share, impacted by expenses of $24.4 million, or $0.10 per share, associated with a single Strensiq manufacturing campaign and expenses of $112.0 million, or $0.47 per share, related to three strategic license agreements. Q1 2014 GAAP EPS was $0.79 per share, which included a benefit of $0.31 per share related to reimbursement of shipments in prior years.
- Q1 2015 non-GAAP EPS was $1.28 per share, impacted by an expense of $24.4 million, or $0.11 per share, associated with a single Strensiq manufacturing campaign. Q1 2014 non-GAAP EPS was $1.53, which included a benefit of $0.37 per share related to reimbursement of shipments in prior years.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the three months ended March 31, 2015. The Company reported net product sales of Soliris® (eculizumab) of $600.3 million, compared to $566.6 million for the same period in 2014 which included reimbursement of $87.8 million from shipments in prior years related to an agreement with the French government. Despite increasing currency headwinds, the year-on-year increase in Q1 net product sales was 25 percent, excluding the $87.8 million recognized in the year-ago quarter. This increase in revenue reflected steady additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS) commencing Soliris treatment across the Company's 50-country global platform.

"In Q1, we provided Soliris to an increasing number of patients with PNH and aHUS worldwide while preparing for the global launch of Strensiq. At the same time, we are developing the broadest pipeline in our history, with three ongoing registration trials with eculizumab, four additional highly innovative molecules in clinical development, and our recently strengthened portfolio of seven complement inhibitors progressing through research and development," said David Hallal, Chief Executive Officer of Alexion. "Throughout the remainder of the year, we will serve an increasing number of patients with PNH and aHUS, and launch Strensiq globally, while continuing to advance our late-stage pipeline as we drive toward as many as seven new indications or product approvals through 2018."

First Quarter 2015 Financial Results

First Quarter 2015 GAAP Financial Results

Alexion reported GAAP net income of $91.3 million, or $0.45 per share, in Q1 2015 compared to Q1 2014 GAAP net income of $159.4 million, or $0.79 per share. Q1 2015 EPS was impacted by $24.4 million, or $0.10 per share, related to an expense associated with a single Strensiq manufacturing campaign and expenses of $112.0 million, or $0.47 per share, related to three strategic license agreements. Q1 2014 GAAP EPS included $0.31 per share related to the reimbursement of shipments in prior years.

On a GAAP basis, operating expenses for Q1 2015 were $427.2 million, compared to $324.2 million for Q1 2014. GAAP R&D expenses for Q1 2015 were $221.1 million, compared to $191.5 million for Q1 2014. GAAP SG&A expenses were $187.1 million for Q1 2015, compared to $129.3 million for Q1 2014. The increase in GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's global operations, including preparation for the launch of Strensiq.

First Quarter 2015 Non-GAAP Financial Results

Alexion's non-GAAP operating results are GAAP operating results adjusted for the impact of certain items described in the accompanying tables. A full reconciliation of GAAP results to non-GAAP results is included later in this press release.

The Company reported non-GAAP net income of $262.0 million, or $1.28 per share, in Q1 2015, compared to non-GAAP net income of $312.6 million, or $1.53 per share, in Q1 2014. Q1 2015 EPS was impacted by $24.4 million, or $0.11 per share, related to an expense associated with a single Strensiq manufacturing campaign. Q1 2014 non-GAAP EPS included a benefit of $0.37 per share related to the reimbursement of shipments in prior years.

Alexion's non-GAAP operating expenses for Q1 2015 were $254.3 million, compared to $195.9 million for Q1 2014. Non-GAAP R&D expenses for Q1 2015 were $97.5 million, compared to $81.5 million for Q1 2014. Non-GAAP SG&A expenses for Q1 2015 were $156.8 million, compared to $114.3 million for Q1 2014. The increase in non-GAAP SG&A expenses primarily reflected costs associated with the expansion of the Company's global operations, including preparation for the launch of Strensiq.

Balance Sheet

As of March 31, 2015, the Company had $1.925 billion in cash, cash equivalents and marketable securities compared to $1.962 billion at December 31, 2014. During the quarter, our positive cash flows from operations were offset by $112.0 million in upfront payments for three strategic license agreements and $60.0 million related to our share repurchase program.

Research and Development Progress:

Alexion has development programs underway with highly innovative product candidates that have the potential to become transformative therapies for patients with severe and rare disorders.

Strensiq™ (Asfotase Alfa)

- The regulatory processes for Strensiq for patients with hypophosphatasia are ongoing in the U.S., Europe and Japan.

Rare Disease Programs With Eculizumab

- **Neurology: Myasthenia Gravis (MG)** - Enrollment and dosing are ongoing in the REGAIN study, a single, multinational, placebo-controlled, registration trial in refractory MG.
- **Neurology: Neuromyelitis Optica (NMO)** - Enrollment and dosing are ongoing in the PREVENT study, a single, multinational, placebo-controlled, registration trial in relapsing NMO.
- **Kidney Transplant: Delayed Graft Function (DGF)** - Alexion is enrolling patients in the PROTECT study, a single, multinational DGF prevention registration trial.
- **Kidney Transplant: Antibody-Mediated Rejection (AMR)** - Alexion will report preliminary data from the Phase 2 deceased-donor trial at the American Transplant Congress. Alexion has plans to commence an AMR treatment trial.

Complement Inhibitor Portfolio

During Q1, Alexion progressed 3 clinical development programs and strengthened its preclinical portfolio of complement inhibitors.

- **ALXN 1210 and ALXN 5500:** The Company advanced Phase 1 studies with its first two next-generation Soliris molecules.
- **ALXN 1007:** Enrollment and dosing are ongoing in two Phase 2 proof-of-concept studies in patients with graft versus host disease involving the lower gastrointestinal tract (GI-GVHD) and antiphospholipid syndrome (APS), two severe, autoimmune diseases with potentially life-threatening complications.
- **Additional Preclinical Programs:** During the quarter, Alexion strengthened its complement inhibitor pipeline with two additional complement inhibitors, bringing its preclinical portfolio to 4 innovative programs across diverse platforms.

cPMP Replacement Therapy (ALXN 1101):

- A synthetic cPMP bridging study in patients with molybdenum cofactor deficiency (MoCD) Type A is ongoing and enrollment in a natural history study is also ongoing. Alexion received Breakthrough Therapy designation for its cPMP replacement therapy in 2013.

2015 Financial Guidance

Alexion is reiterating all items of its 2015 guidance as provided in the press release issued on January 29, 2015:

- Worldwide net product sales are expected to be within a range of $2.55 to $2.6 billion, which includes an approximately negative 6 percent, or $160 million, foreign exchange impact compared to 2014 exchange rates.
- Non-GAAP earnings per share for the year are expected to be $5.60 to $5.80, which includes an approximately $0.35 negative foreign exchange impact compared to 2014 exchange rates.
- 2015 guidance is based on current exchange rates remaining unchanged for the remainder of the year.

On a non-GAAP basis, Alexion is reiterating 2015 financial guidance as follows:

Cost of sales	8% to 9% of net product sales
Research and development	$440 to $470 million
Selling, general and administrative	$620 to $650 million
Effective tax rate	7% to 9%
Diluted shares outstanding	205 million

Conference Call/Webcast Information:

Alexion will host a conference call/audio webcast to discuss matters mentioned in this release. The call is scheduled for today, April 23, at 10:00 a.m., Eastern Time. To participate in this call, dial 1-877-874-1571 (USA) or +1-719-325-4789 (International), passcode 8676867 shortly before 10:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at 1:00 p.m., Eastern Time. The replay number is 1-888-203-1112 (USA) or +1-719-457-0820 (International), passcode 8676867. The audio webcast can be accessed on the Investor page of Alexion's website at: http://ir.alexionpharm.com.

About Soliris® (eculizumab)

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris is approved in the U.S. (2007), European Union (2007), Japan (2010) and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis. PNH is a debilitating, ultra-rare and life-threatening blood disorder, characterized by complement-mediated hemolysis (destruction of red blood cells). Soliris is also approved in the U.S. (2011), European Union (2011), Japan (2013) and other countries as the first and only treatment for patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). aHUS is a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated TMA. Soliris is not indicated for the treatment of patients with Shiga-toxin *E. coli*-related hemolytic uremic syndrome (STEC-HUS). For the breakthrough medical innovation in complement inhibition, Alexion and Soliris have received some of the pharmaceutical industry's highest honors: the Prix Galien USA (2008, Best Biotechnology Product) and France (2009, Rare Disease Treatment).

More information including the full U.S. prescribing information on Soliris is available at www.soliris.net.

About Alexion

Alexion is a biopharmaceutical company focused on serving patients with severe and rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition and has developed and markets Soliris® (eculizumab) as a treatment for patients with PNH and aHUS, two debilitating, rare and life-threatening disorders caused by chronic uncontrolled complement activation. Soliris is currently approved in nearly 50 countries for the treatment of PNH, and in nearly 40 countries for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris in additional severe and ultra-rare disorders beyond PNH and aHUS, and is developing other highly innovative biotechnology product candidates across multiple therapeutic areas. This press release and further information about Alexion can be found at www.alexion.com.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2015, assessment of the Company's financial position and commercialization efforts, medical benefits and commercial potential for Soliris for PNH and aHUS and other potential indications, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, commercial potential associated with the expected launch of Strensiq in 2015, and plans for clinical programs for each of our product candidates. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, decisions of regulatory authorities regarding marketing approval or material limitations on the marketing of Soliris for PNH and aHUS and other potential indications or Strensiq for HPP, delays, interruptions or failures in the manufacture and supply of Soliris, Strensiq, and our other product candidates, progress in establishing and developing commercial infrastructure, failure to satisfactorily address the issues raised by the FDA in regulatory correspondence, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations in the disease studied or other diseases, the risk that strategic transactions will not result in short-term or long-term benefits, the possibility that current results of commercialization are not predictive of future rates of adoption of Soliris in PNH, aHUS or other diseases, the possibility that clinical trials of our product candidates could be delayed or that additional research and testing is required by regulatory agencies, the adequacy of our pharmacovigilance and drug safety reporting processes, the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of Soliris at acceptable rates or at all, the risk that estimates regarding the number of patients with PNH, aHUS or other diseases are inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the U.S. Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Annual Report on Form 10-K for the period ended December 31, 2014 and in our other filings with the U.S. Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

In addition to financial information prepared in accordance with GAAP, this news release also contains non-GAAP financial measures that Alexion believes, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. The non-GAAP results exclude the impact of the following GAAP items: share-based compensation expense, acquisition-related costs, upfront and milestone payments related to license and collaboration agreements, intangible asset impairments, restructuring expenses, and non-cash taxes. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliation of GAAP to Non-GAAP Financial Results for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three month periods ended March 31, 2015 and 2014.

(Tables Follow)

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31	
	2015	**2014**
Net product sales	$ 600,333	$ 566,616
Cost of sales	69,399	32,939
Operating expenses:		
Research and development	221,080	191,457
Selling, general and administrative	187,116	129,291
Impairment of intangible asset	-	3,464
Acquisition-related costs	11,979	(38)
Restructuring expenses	7,052	-
Total operating expenses	427,227	324,174
Operating income	103,707	209,503

Other income	3,238	2,408
Income before income taxes	106,945	211,911
Income tax provision	15,622	52,557
Net income	$ 91,323	$ 159,354
Earnings per common share		
Basic	$ 0.46	$ 0.81
Diluted	$ 0.45	$ 0.79
Shares used in computing earnings per common share		
Basic	199,361	197,797
Diluted	202,034	201,804

ALEXION PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL RESULTS
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31	
	2015	**2014**
Net income reconciliation:		
GAAP net income	$ 91,323	$ 159,354
Share-based compensation expense	42,797	23,840
Acquisition-related costs (1)	11,979	(38)
Upfront and milestone payments related to license and collaboration agreements (2)	112,500	101,925
Impairment of intangible assets	-	3,464
Restructuring expenses (3)	7,052	-
Non-cash taxes (4)	(3,672)	24,054
Non-GAAP net income	$ 261,979	$ 312,599
GAAP earnings per share - diluted	$ 0.45	$ 0.79
Non-GAAP earnings per share - diluted	$ 1.28	$ 1.53
Shares used in computing diluted earnings per share (GAAP)	202,034	201,804
Shares used in computing diluted earnings per share (non-GAAP)	204,383	204,830
Cost of sales reconciliation:		
GAAP cost of sales	$ 69,399	$ 32,939
Share-based compensation expense	(1,409)	(883)
Non-GAAP cost of sales	$ 67,990	$ 32,056
Research and development reconciliation:		
GAAP research and development	$ 221,080	$ 191,457
Share-based compensation expense	(11,084)	(7,984)
Upfront and milestone payments related to license and collaboration agreements (2)	(112,500)	(101,925)
Non-GAAP research and development	$ 97,496	$ 81,548

Selling, general and administrative reconciliation:		
GAAP selling, general and administrative	$ 187,116	$ 129,291
Share-based compensation expense	(30,304)	(14,973)
Non-GAAP selling, general and administrative	$ 156,812	$ 114,318
Income tax provision reconciliation:		
GAAP income tax provision	$ 15,622	$ 52,557
Non-cash taxes (4)	3,672	(24,054)
Non-GAAP income tax provision	$ 19,294	$ 28,503

(1) Acquisition-related costs represent changes in fair value of contingent consideration.

(2) During the three months ended March 31, 2015, the Company entered into three agreements for the clinical development and commercialization of drug products. The Company recorded research and development expense for upfront payments of $112.0 million.

(3) In October 2014, the Company announced plans to relocate its European headquarters from Lausanne to Zurich, Switzerland. The Company recorded restructuring expenses of $7.1 million during the three months ended March 31, 2015 related to employee costs.

(4) Non-cash taxes represents the adjustment from GAAP tax expense to the amount of taxes that are payable in cash in the current period.

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2015	December 31, 2014
Cash and cash equivalents	$ 916,814	$ 943,999
Marketable securities	1,008,278	1,017,567
Trade accounts receivable, net	479,883	432,888
Inventories	174,498	176,441
Prepaid expenses and other current assets	273,514	225,134
Property, plant and equipment, net	440,487	392,248
Intangible assets, net	587,035	587,046
Goodwill	254,073	254,073
Other assets	280,343	172,566
Total assets	$4,414,925	$ 4,201,962
Accounts payable and accrued expenses	$ 361,276	$ 439,248
Deferred revenue	106,616	58,837
Current portion of long-term debt	45,500	48,000
Other current liabilities	67,047	60,655
Long-term debt, less current portion	-	9,500
Contingent consideration	126,862	116,425
Facility lease obligation	114,912	107,099
Other liabilities	75,810	60,180
Total liabilities	898,023	899,944
Total stockholders' equity	3,516,902	3,302,018
Total liabilities and stockholders' equity	$4,414,925	$ 4,201,962

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Source: Alexion Pharmaceuticals, Inc.